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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,618	04/19/2001	Brett T. Haarala	10123/01101	3578
7590 11/14/2006			EXAMINER	
Fay Kaplun & Marcin, LLP 150 Broadway Suite 702 New York, NY 10038			KEASEL, ERIC S	
			ART UNIT	PAPER NUMBER
			3753	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/838,618

**Applicant(s)**

HAARALA ET AL.

**Examiner**

Eric Keasel

**Art Unit**

3753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 and 47-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-46 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-42 and 47-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 25, 2002.
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (US 5,752,970).

Yoon discloses a medical device (20) having an elongate catheter (22) with an external surface and an internal surface defining an internal lumen (Figure 3) and having a compound slit located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (unlabelled Figure 2). The slit of Yoon is biased closed

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and would inherently open due to difference in pressure between the lumen and the ambient.

The slit of Yoon is also configured to inherently allow the flaps to flex outward when the internal pressure exceeds the external pressure by a second amount.

5. Claims 43, 44 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Eaton (US 3,303,847).

Eaton discloses a medical device having an elongate catheter (5) with an external surface and an internal surface defining an internal lumen and having a compound slit (8, 9) located at a generally hemispherical distal end portion (6) of the catheter and extending from the external surface to the internal surface (see Fig. 4). The slit of Eaton is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Eaton is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between the pressure ambient pressure and the pressure inside the lumen and to flex outward when the internal pressure exceeds the external pressure by a second amount.

6. Claims 43, 44, 46, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferguson (US 2,063,424).

Ferguson discloses a medical device having an elongate catheter with an external surface and an internal surface defining an internal lumen and having a compound slit (3, 4, 5) located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (see Fig. 1). The slit of Ferguson is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Ferguson is also

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configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between ambient pressure and the pressure inside the lumen and to flex outward when the internal pressure exceeds the external pressure by a second amount.

7. Claims 43, 44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamauchi (US 2,063,424).

Yamauchi discloses a medical device having an elongate catheter with an external surface and an internal surface defining an internal lumen and having a compound slit (6) located at a generally hemispherical distal end portion of the catheter and extending from the external surface to the internal surface (see Fig. 3). The slit of Yamauchi is biased closed and opens due to difference in pressure between the lumen and the ambient. The slit of Yamauchi is also configured to inherently allow the flaps to flex into the lumen based on a predetermined pressure difference between ambient pressure and the pressure inside the lumen and to flex outward when the internal pressure exceeds the external pressure by a second amount.

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eaton in view of Engelson et al. (US Patent Number 5,798,018).

Eaton fails to disclose the collar. Engelson et al. disclose a collar (130) used on a similar catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the collar of Engelson et al. with the catheter of Eaton so that the catheter can be radiographed visually as taught by Engelson et al.

10. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon in view of Engelson et al. (US Patent Number 5,798,018).

Yoon fails to disclose the collar. Engelson et al. disclose a collar (130) used on a similar catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the collar of Engelson et al. with the catheter of Yoon so that the catheter can be radiographed visually as taught by Engelson et al.

***Response to Arguments***

11. Applicant's arguments filed August 22, 2006 have been fully considered but they are not persuasive (except for Yoon as applied to claim 61).

Applicant argues that the device of Yoon does not allow flow from outside the catheter to inside based on a pressure difference. This is persuasive and the rejection of claim 61 is withdrawn. However, claim 43 is broader. The valve flaps open out whether due to a force of a solid object or the force of a differential fluid pressure.

Applicant does not appear to understand the Eaton reference. Applicant cites a section that explicitly states that the container is squeezed to increase the fluid pressure and this increase in fluid pressure internal to the catheter causes the slit valve to open. Eaton's disclosure from 1967 clearly anticipates the overly broad claimed subject matter.

Applicant argues that the device of Ferguson does not meet the dictionary definition of catheter. Ferguson discloses a tubular device that is inserted into a body cavity (mouth) to inject fluids (milk). Applicant argues that babies bite the nipple and do not apply any suction. The examiner disagrees. In fact this is explicitly disclosed in the Yamauchi reference.

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication should be directed to Eric Keasel at telephone number (571) 272-4929, who can normally be reached Monday-Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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